## REMARKS

The Final Office Action mailed June 3, 2004 has been received and reviewed. Claims 1 through 15 and 21 through 24 are noted as pending in the Final Office Action. Claims 16 through 20 were earlier canceled. Applicants propose to amended claim 14. Reconsideration of the application as proposed to be amended is respectfully requested.

Applicants note the withdrawal of the 35 U.S.C. § 112, first paragraph rejection of claims 1 through 7 and the withdrawal of the 35 U.S.C. § 102(b) rejection of claims 1 through 15.

### 35 U.S.C. § 112 First Paragraph Rejections

Claims 1 through 15 and 21 through 24 stand rejected in the Final Office Action as assertedly failing to comply with the written description requirement under the first paragraph of 35 U.S.C. § 112. The Final Office Action states that "the claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." (Final Office Action at page 2). Specifically, the Office Action states that it "does not find specific support for the new limitations recited in the claims.

Applicants respectfully traverse this rejection. As described in M.P.E.P. § 2163.02:

> Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed.... **The subject matter of the claim need not be described literally (i.e. using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement.** If a claim is amended to include . . . terminology not present in the application as filed, involving a departure from, addition to or deletion from the disclosure as filed, the examiner should conclude that the claimed subject matter is not described in the application.

The exact language of a claim is thus not required to be found in description, so long as the subject matter of the claim is sufficiently described therein.

With respect to independent claims 1 and 8, the Final Office Action states that these claims now recite 'said first member of the specific binding pair not being a viral antigen naturally expressed on said delivery vehicle.'" The Final Office Action notes that the prior Amendment identifies [0019] and [0023] as part of the specification providing support for such

claims. With respect to paragraph [0019], the Final Office Action states that "there is nothing in" paragraph [0019] "to exclude the use of a native viral antigen as the first member of the specific binding pair." (Final Office Action at page 3). As a first point, applicants respectfully submit that paragraph [0016] of the specification makes it clear that the gene delivery vehicle is preferably "no longer an infectious virus particle" but "[i]nstead of having its regular infectivity, it is provided with a member of a specific binding pair, either as a part of its envelope or as a part of its capsid." Further, in paragraphs [0046] through [0051] of the specification, which disclose substances for exposure on virus surfaces and the providing of such substances to the envelope or capsid of viruses, "heterologous" protein or peptide is used an a first member of the specific binding pair in all of the examples provided. No native viral antigen is mentioned therein for such use. Thus, it is clear from the specification that a native viral antigen is not contemplated as the first member of the specific binding pair. Accordingly, no new matter is present and the rejection should be withdrawn.

Turning to the language identified in the Final Office Action, paragraph [0019] of the specification states:

> **A similar approach has been disclosed and is described above as approach no. 3. In this approach, however, the vehicle has not been provided with an additional member of a specific binding pair, but a viral antigen (the envelope glycoprotein) itself is the member of a specific binding pair being recognized by an antibody**. Apart from the drawback of having to make a new specific dual-antibody complex for every delivery system, an even more important drawback is that all antigens have to be bound to an antibody because, otherwise, the vehicle will retain its capability of infecting its regular host cells, whereas for the gene delivery vehicles according to the invention these glycoproteins are preferably (if not necessarily) not present or altered to impair their normal function. (emphasis added).

The language identified by the Final Office Action in paragraph [0019], thus refers to an identified prior art approach, discussed in the Background section of the specification at paragraph [0010], and, identified as approach number 3 ("bridging the viral envelope glycoprotein to a molecule on the target cell through a complex of an antibody directed against the viral envelope glycoprotein and a peptide ligand for the molecule on the target cell (Etienne-Julan et al.)"). Paragraph [0019] thus describes a prior approach and differentiates the current approach therefrom.

> With respect to paragraph [0023], the Final Office Action states that it:
>
> refers to several examples of specific binding pairs, such as antibody and the corresponding antigen, and states that "[i]n many instances, members of these binding pairs will not be normally present in the envelope or capsid of a virus and will thus also not normally be present on the gene delivery vehicles according to the invention." Again, there is nothing in this paragraph indicating that the claimed invention is intended to exclude native viral antigens as the first member of the specific binding pair.

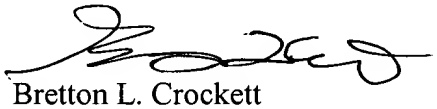
The sentence of paragraph [0023] cited in the Office Action, thus notes that "members of these binding pairs **will not be normally present in the envelope or capsid of a virus and will thus also not normally be present on the gene delivery vehicles** according to the invention" (emphasis added). Applicants thus respectfully submit that this language provides further support by indicating that embodiments wherein a native viral antigen is not used are normally within the scope of the presently claimed invention. The Final Office Action even acknowledges this, stating "the paragraph emphasizes what would need to be done for embodiments where a native viral antigen is not being used as the first member of the specific binding pair." (Final Office Action at page 3). Accordingly, further support for the claim language may be found in paragraphs [0019] and [0023].

The Final Office Action further states that claim 14 recites: "by altering the capsid or envelope of said virus," and that applicants "have not pointed to any support in the specification as-filed for this new limitation." (Final Office Action at page 3). Basis for these claim elements can be found in paragraphs [0016] and [0046] through [0051] of the as-filed application. In order to ensure the clarity of the claim, applicants propose to amend claim 14 herein to recite: "The kit of parts according to claim 8, wherein said virus is derived from a virus selected from the group consisting of adenoviruses, adeno-associated viruses, and retroviruses by **providing the capsid or envelope of said virus with the first member of the specific binding pair**." (emphasis added). Support for this recitation can be found in the as-filed specification, in paragraph [0016]. Accordingly, applicants request the amendment be entered and claim 14 be allowed.

## CONCLUSION

All pending claims are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Office determine that additional issues remain which might be resolved by a telephone conference, the Examiner is respectfully invited to contact applicants' attorney.

Respectfully submitted,



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Date: July 19, 2004
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